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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,930	05/30/2001	Blake J. Roessler	UM-06192	7740

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EXAMINER
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EPPS, JANET L

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 01/13/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/867,930

Applicant(s)

ROESSLER ET AL.

Examiner

Janet L Epps-Ford, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election of Group I, claims 1-13, in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1 and 4-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Dederen et al.

Claims 1, and 4-13 are drawn to (1) a composition comprising a nanoemulsion formulation, wherein the nanoemulsion formulation comprises an aqueous component, an oil component, and a surfactant mixture component, wherein said surfactant mixture component comprises a low HLB value surfactant and a high HLB value surfactant; (4) wherein the low HLB surfactant has an HLB between approximately 3.3 and 5.3 and the high HLB value surfactant has an HLB value between approximately 14.0 and 16.0;(5) wherein said nanoemulsion formulation comprises a biological agent;(6) wherein said nanoemulsion does not contain short-chain alcohols;(7) wherein said low HLB surfactant is present in a greater amount

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than said high HLB value surfactant;(8) wherein said surfactant mixture component comprises a low HLB value non-ionic surfactant and a high HLB value non-ionic surfactant.

Claims 9-10 are drawn to (9) a composition comprising a nanoemulsion formulation that permits a skin permeation rate of at least 0.447% per hour for a biological agent in said nanoemulsion formulation; (10) wherein said skin permeation rate is selected from at least 0.519% per hour, at least 0.615% per hour, and at least 0.823% per hour.

Claims 11-12 are drawn to (11) a composition comprising a nanoemulsion formulation that permits an expression vector to express a recombinant peptide at a mean level of at least 57.0 pg/cm<sup>2</sup> in cells; (12) wherein said recombinant peptide is expressed at a mean level selected from at least 100.0 pg/cm<sup>2</sup>, at least 285.0 pg/cm<sup>2</sup>, and at least 376.0 pg/cm<sup>2</sup>.

Claim 13 is drawn to a composition comprising a nanoemulsion formulation that permits an expression vector to express RNA transcripts at a level of at least  $5.0 \times 10^4$  transcripts/cm<sup>2</sup> in cells.

On page 13, lines 14-16, of the specification as filed, Applicants define the term “nanoemulsion formulation” as referring to “a composition comprising an aqueous component, an oil component, and a surfactant mixture component.” Therefore any composition that comprises these elements will be interpreted as reading on a “nanoemulsion formulation.” Additionally, page 26, line 22, of the specification as filed, defines examples of “biological agents” as including carbohydrates.

Dederen et al. disclose oil in water emulsions including an oil emulsifier and a combination of polysaccharides to provide enhanced stability even at low emulsifier stabiliser levels. The emulsifier stabiliser system of Dederen et al. provides stable emulsions without

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dominating system rheology, particularly viscosity. Thus, the emulsions can have a low viscosity suitable for formulation as milks or thin lotions, or can be thickened, desirably by thickening agents other than the Xanthan and/or polyglucomannan, to provide emulsion creams or gels. This enables the system to be used very flexibly in end use applications. The emulsifier is desirably a non-ionic emulsifier and particularly is a combination of a low HLB and a high HLB emulsifier and can be formulated with conventional alcohol ethoxylate (EO) surfactants or from non-EO surfactants, such as sucrose ester high HLB surfactants and citrate or sorbitan ester low HLB surfactants. Additionally, Dederen et al. teach that high HLB refers to HLB values of more than about 10, or more than about 12, and low HLB values refers to values of less than about 8 (see page 4, paragraph [0032], and page 5, paragraph [0034]. Additionally, Dederen et al. teach that formulations comprising an excess of hydrophobic emulsifiers (having a low HLB) seems less detrimental to stability and may contribute more to a desired emulsion rheology in comparison to formulations having an excess of hydrophilic emulsifiers (having a high HLB) (see paragraph [0035] and lines 1-5 of paragraph [0032].

Moreover, since Dederen et al. discloses a nanoemulsion formulation according to the present invention, absent evidence to the contrary, the nanoemulsion formulations of Dederen et al. would function to permit a skin permeation rate of at least 0.447% per hour for a biological agent in said nanoemulsion formulation; wherein said skin permeation rate is selected from at least 0.519% per hour, at least 0.615% per hour, and at least 0.823% per hour; permit an expression vector to express a recombinant peptide at a mean level of at least 57.0 pg/cm<sup>2</sup> in cells; wherein said recombinant peptide is expressed at a mean level selected from at least 100.0

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pg/cm<sup>2</sup>, at least 285.0 pg/cm<sup>2</sup>, and at least 376.0 pg/cm<sup>2</sup>, and furthermore to permit an expression vector to express RNA transcripts at a level of at least  $5.0 \times 10^4$  transcripts/cm<sup>2</sup> in cells.

Dederen et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dederen et al.

Claims 2-3 are drawn to the composition of claims 1, wherein the ratio of said low HLB value surfactant to said high HLB value surfactant is at least 2:1 or at least 3:1.

Discussion of Dederen et al. as set forth in the above rejection is incorporated here. However, Dederen et al. does not specifically teach a nanoemulsion formulation comprising wherein the ration of low HLB value surfactant to said high HLB value surfactant is at least 2:1 or at least 3:1.

Dederen et al. does teach compositions comprising both a high HLB emulsifier (or surfactant) and a low HLB emulsifier, wherein that high HLB refers to HLB values of more than about 10, or more than about 12, and low HLB values refers to values of less than about 8 (see page 4, paragraph [0032], and page 5, paragraph [0034]. In addition, Dederen et al. favor the use of an excess of hydrophobic emulsifier (i.e. low HLB; paragraph [0032]). Although Dederen et al. does not specifically recite wherein the ratio of low HLB value surfactant to said high HLB

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value surfactant is at least 2:1 or at least 3:1, the ratios of low HLB surfactants to high HLB surfactants recited in the instant claims fall within the scope of the invention of Dederen et al., wherein nanoemulsion formulations comprising an excess in low HLB surfactants are preferred.

It would have been obvious to one of ordinary skill in the art at the time of filing to modify the teachings of Dederen et al. by optimizing the ratio of low HLB surfactant to high HLB surfactant to produce the compositions of the present invention. One of ordinary skill in the art would have been motivated to optimize this ratio since the ratio of low HLB to high HLB is disclosed in the prior art as being critical for determining the stability of an emulsion, see paragraph [0035]. Moreover, “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), MPEP § 2144.05.

Therefore, the invention as a whole is *prima facie* obvious over Dederen et al.

### ***Drawings***

6. New corrected drawings must be filed with the changes indicated on the attached PTO-948 incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the “Notice of Allowability.”

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Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

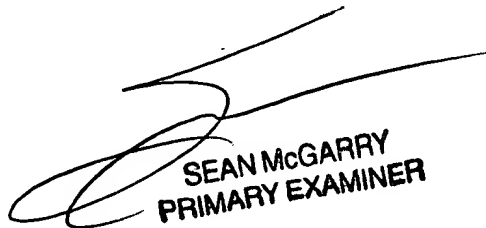
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 9:00AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps-Ford, Ph.D.  
Examiner  
Art Unit 1635

*JLE*  
January 8, 2003

  
SEAN McGARRY  
PRIMARY EXAMINER